REA Date Stamp

USUHS FORM 3204A
RESEARCH INVOLVING HUMAN PARTICIPANTS
(continuing/annual review)

SECTION I PROTOCOL INFORMATION

Protocol No.: _____

Principal Investigator: _____

Department: _____ **Phone** _____

E-Mail: _____ **Pager or Other Phone Number** _____

Project Title: _____

SECTION II STATUS OF THE STUDY {Mark the status of the study (a-g) and note the specific information that must be submitted}.

a. _____ **No participants accrued/data collected in this study** - termination requested. [Complete section III only].

b. _____ **Participant accrual/data collection for this study is pending -** continued approval requested. [Submit Sections III and IV (2, 8, and 10)].

c. _____ **Active with ongoing participation of subjects/data collection: Participant accrual/data collection not completed.** [Submit Sections III and IV (1 and 3-11)].

d. _____ **Active with ongoing participation of subjects: Participant accrual completed.** [Submit Sections III and IV (1 and 3-9)].

e. _____ **Active with follow-up of participants only.** [Submit Sections III and IV (4 only)].

f. _____ **Active with data analysis only: Subject participation/data collection completed.** [Submit Sections III and IV (1 - 4).]

g. _____ **Completed. Participants will not be followed/data analysis completed.** Date of Completion: _____ [Submit Sections III and IV (1 and 3-9) as a final human participant use report.

SECTION III. CERTIFICATION OF PRINCIPAL INVESTIGATOR

Signature certifies that the above titled research has been/will be conducted in full compliance with the DHHS/FDA Regulations and USUHS IRB requirements/policies governing human participant research. It is understood that IRB continuing review is required in order to maintain study approval and that **ANY** changes in the study/methodology which affect the participants must be approved by the IRB prior to implementation. Alternatively, if the study has never been

initiated and you are requesting termination (II[a] above), your signature verifies this request. If the study is completed (II[g] above), the information provided on this form represents an accurate final human research report.

Signature of Principal Investigator _____ Date _____

SECTION IV SUMMARY OF RESEARCH (use additional sheets as necessary)

DEMOGRAPHIC INFORMATION

1. **Target Accrual number:** What is the target accrual number approved by the IRB? _____

2. **Non-accrual:** If no participants have been accrued since the last IRB review, the reason(s) for non-accrual must be provided.

3. **Number of participants accrued since last review:** How many participants have been accrued since last review?

Total number of participants accrued since activation of the study: _____

Adults	American Indian or Alaska Native	Asian	Black or African American	Hispanic or Latino	Native Hawaiian or Other Pacific Islander	White or Caucasian	Other or Unknown	Total
Male								
Female								
Total Adults								

Children	American Indian or Alaska Native	Asian	Black or African American	Hispanic or Latino	Native Hawaiian or Other Pacific Islander	White or Caucasian	Other or Unknown	Total
Male								
Female								
Total Children								

STUDY RESULTS

4. **Study Progress/Results:** Provide a brief summary of study progress/results (preliminary or final) obtained in the study. If the study is part of a cooperative group or multi-center trial, a copy of the most recent group-wide progress report must be attached.

ADVERSE EVENTS AND PROBLEMS

5. **Unanticipated adverse event(s):** From initial approval of the study to the present, has any participant enrolled in your study suffered an unanticipated adverse event? If the answer is yes, specify the total number of events, date(s) and summarize briefly the overall nature and significance of the adverse event(s).

PARTICIPANT WITHDRAWAL

6. **Involuntary participant withdrawal:** Was any participant withdrawn from your study because of medical complications or other problems? If the answer is yes, provide a brief description of the medical complication/problem for each participant who was involuntarily withdrawn.

7. **Voluntary participant withdrawal:** Did any participant voluntarily withdraw from your study for non-medical reasons? If the answer is yes, provide a brief description of any known reason(s) for each participant who voluntarily withdrew from the study.

CURRENT RISK/BENEFIT ASSESSMENT

8. **Current Risk/Benefit Assessment:** Has anything occurred since the last IRB review that may have altered the risk/benefit relationship? If the answer is yes, provide a current assessment, in your opinion, of the risk/benefit relationship based upon study results, adverse events, or other factors.

INFORMED CONSENT EVALUATION

9. **Informed consent process:** Did any problems occur relative to the obtainment and documentation of informed consent since the last IRB review? If the answer is yes, please provide a brief description of the problems.

10. **Informed consent document:** Is the approved informed consent document still acceptable (i.e., the information contained in the document is accurate and complete and there is no new information, which should be disclosed to the participant)? ***If in your opinion the approved informed consent document is still acceptable, this must be stated and a clean copy of the form(s) must be submitted with this form on USUHS letterhead for a continuing approval stamp.*** If, however, revisions are necessary, this must be stated and a new USUHS Form 3204 must be submitted along with this annual review

11. **Equity or consultative relationship:** Have any investigators developed an equity or consultative relationship with a non-USUHS source related to this protocol which might be considered to be a conflict of interest? ***(If yes, please append a statement of disclosure.)***